(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 9 June 2005 (09.06.2005)

PCT

(10) International Publication Number WO 2005/051349 A2

(51) International Patent Classification⁷:

A61K 9/00

(21) International Application Number:

PCT/IB2004/003872

(22) International Filing Date:

24 November 2004 (24.11.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

964/CHE/2003 25 November 2003 (25.11.2003) IN 930/CHE/2004 17 September 2004 (17.09.2004) IN

- (71) Applicant (for all designated States except US): AU-ROBINDO PHARMA LTD. [IN/IN]; Plot No. 2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): ALURI, Phanindrudu [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN). BABU, Justin [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN). RAO, Shaik, Srinivasa [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN). GOGIA, Ashish [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN).

- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

Published:

 without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITIONS OF MIRTAZAPINE

(57) Abstract: The present invention relates to pharmaceutical compositions of mirtazapine or its pharmaceutically acceptable salts. More particularly, the present invention relates to solid unit dosage forms of anhydrous mirtazapine or its pharmaceutically acceptable salts suitable for oral administration. The present invention also relates to a process for the preparation of pharmaceutical compositions of mirtazapine or its pharmaceutically acceptable salts.